K030526

DEC 2 9 2004

510(k) SUMMARY

NAME OF FIRM:	SpineVision, Inc. 3003 Summit Blvd., Suite 1400 Atlanta, GA 30319 Phone: 404-460-5077
510(K) CONTACT:	Lynnette Whitaker Vice President, Regulatory Affairs 574-269-9776
TRADE NAME:	PediGuard™ Nerve Detector System
COMMON NAME:	Nerve Stimulator
CLASSIFICATION:	874.1820
DEVICE PRODUCT CODE:	Product code: 77 ETN
SUBSTANTIALLY EQUIVALENT DEVICES:	Neurosign 800, Magstim Company, Ltd. (K980148) NuVasive, Inc.'s INS-1 Intraoperative Nerve Surveillance System (K002677) TOEI Electric Co., Ltd.'s JUSTWO Model TME-601 Root Apex Locator (K022020)

DEVICE DESCRIPTION AND INTENDED USE:

The PediGuard System is a hand held, battery operated bi-polar probe that is comprised of the following components: (1) a stainless steel shaft; (2) a hollow plastic handle; and (3) an electronic cartridge. Its components are manufactured from stainless steel and plastics according to ASTM and USP requirements.

The PediGuard is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by

administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The components of the PediGuard Nerve Monitoring System are similar in design, material, and intended use to other nerve monitoring systems that have been cleared by FDA for spinal use. Testing was performed to demonstrate the equivalence of the construct design to currently marketed spinal systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2004

Ms. Lynnette Whitaker
Vice President, Regulatory Affairs
SpineVision, Inc.
3003 Summit Boulevard, Suite 1400
Atlanta, Georgia 30319

Re: K030526
Trade/Device Name: PediGuard
Regulation Number: 21 CFR 882.1870
Regulation Name: Evoked response electrical stimulator
Regulatory Class: II
Product Code: GWF
Dated: November 24, 2004
Received: November 24, 2004

Dear Ms. Whitaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K030526

Device Name: PediGuard

Indications for Use:

The PediGuard is indicated for use during pedicle screw pilot hole drilling to provide feedback to the surgeon via visual and audible alerts that indicate a change in impedance at the tip of the probe and may indicate contact of the tip with soft tissues and possible vertebral cortex perforation. The PediGuard also is specifically indicated for use in intraoperative electromyographic ("EMG") surveillance to assist in the location and evaluation of spinal nerves during surgery of the spine, by administration of low voltage electrical energy to tissues and nerves at the operative site, and EMG monitoring of muscle groups associated with those nerves.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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